Listing of the Claims

Originally Patented Claims (5,551,427):

1-26. (Cancelled)

Claims Introduced in this Application:

27. (Amended) A process for delivering an angiogenic growth factor to the heart of a patient, including:

penetrating an element of a delivery device into heart tissue; and

with the element so penetrated, delivering an angiogenic growth factor to the tissue through the element.

28. (Amended) A process for treating the heart of a patient, including:

providing a catheter with a tissue penetrating element disposed at a distal end thereof;

inserting at least the distal end of the catheter into a chamber of the heart;

causing the penetrating element, while in the chamber of heart, to penetrate heart tissue; and

after causing the penetrating element to penetrate heart tissue, delivering an angiogenic agent from the penetrating element to surrounding cardiac tissue.

29. (Previously added) An apparatus for locally modifying electrical action within the heart, comprising:

a biocompatible, electrically inactive device including an element for penetrating cardiac tissue to secure the device at a designated site in a heart, to modify electrical action in the cardiac tissue at the designated site; and

a catheter releasably coupled to the device to allow use of the catheter to deliver the device to the designated site, and further to allow a withdrawal of the catheter after securing the device.

30. (Previously added) An apparatus for delivering a pharmacological agent to the heart, including:

a catheter body having a proximal end, a distal end, and adapted to convey a pharmacological agent toward the distal end; and

a tissue penetrating structure releasably coupled to the distal end of the catheter body and adapted to deliver the pharmacological agent from the catheter body into heart tissue.

31. (Previously added) A process for delivering an angiogenic agent to the heart, including:

providing a device having an element adapted to penetrate cardiac tissue;

inserting the device into a heart, and causing the element to penetrate tissue inside the heart; and

delivering an angiogenic agent through the penetrated element into surrounding tissue.

32. (Previously added) The process of claim 27 wherein:

said penetrating the element of the delivery device positions the element inside a chamber of the heart.

33. (Previously added) The process of claim 27 wherein:

the delivery device incorporates a controlled release matrix, and said delivering the angiogenic growth factor includes providing the angiogenic growth factor to the controlled release matrix.

34. (Previously added) The process of claim 27 wherein:

said delivering the angiogenic growth factor comprises providing a controlled release of the angiogenic growth factor over an extended period of time.

35. (Previously added) The process of claim 27 wherein:

at least part of the element is coated with a controlled release matrix, and said delivering the angiogenic growth factor comprises providing the angiogenic growth factor to the controlled release matrix.

36. (Amended) The process of claim 27 wherein:

the delivery device comprises a catheter having a distal end and adapted to support the delivery device at said distal end, and said delivering the angiogenic growth factor includes delivering the angiogenic growth factor through a lumen in the catheter.

37. (Previously added) The process of claim 36 further including:

before said penetrating the element, inserting the distal end of the catheter into a chamber of the heart, and using the catheter to position the element at a site selected for said penetrating.

38. (Previously added) The process of claim 28 wherein:

said delivering the angiogenic agent comprises delivering the angiogenic agent through a lumen in the catheter.

39. (Previously added) The process of claim 28 further including:

after inserting at least the distal end of the catheter into a chamber of the heart, and before causing the tissue penetrating element to penetrate heart tissue, using the catheter to position the tissue penetrating element at a site selected for penetration.

40. (Previously added) The process of claim 28 further including:

after delivering the angiogenic agent, removing the catheter to leave the penetrating element implanted in the heart tissue.

41. (Previously added) The process of claim 28 wherein:

said delivering the angiogenic agent comprises using a controlled release mechanism associated with at least one of the penetrating element and the catheter.

42. (Previously added) The process of claim 28 wherein:

said delivering the angiogenic agent includes providing a controlled release of the angiogenic agent over an extended period of time.

43. (Previously added) The apparatus of claim 29 further including:

a controlled release matrix disposed along the device for supplying a pharmacological agent to the cardiac tissue.

44. (Previously added) The apparatus of claim 29 further including:

an electrode at a distal end of the catheter for sensing electrical action in the cardiac tissue, to facilitate determining the designated site in the heart for penetrating cardiac tissue.

45. (Previously added) The apparatus of claim 29 further including:

a fluid passage through the device, open to an exterior of the device at the penetrating element and at a proximal portion of the device opposite the penetrating element, wherein the catheter incorporates a lumen fluid coupled to the fluid passage at the proximal portion of the device.

46. (Previously added) The apparatus of claim 45 wherein:

the device, at least over an outermost portion thereof that includes an exposed surface, is formed of an electrically conductive material.

47. (Previously added) The apparatus of claim 30 further including:

a controlled release matrix disposed along the tissue penetrating structure for supplying the pharmacological agent to the heart tissue.

48. (Previously added) The apparatus of claim 30 further including:

an electrode at the distal end of the catheter body for sensing electrical action in the heart tissue to facilitate locating a site for penetrating the heart tissue with the tissue penetrating structure.

49. (Previously added) The apparatus of claim 30 further including:

a fluid passage through the tissue penetrating structure, open to an exterior of the tissue penetrating structure at opposite proximal and distal portions thereof.

50. (Previously added) The apparatus of claim 49 wherein:

the catheter body incorporates a lumen fluid coupled to the fluid passage to facilitate conveying the pharmacological agent from the lumen to the heart tissue via the fluid passage.

51. (Previously added) The process of claim 31 wherein:

said device incorporates a controlled release matrix, and said delivering the angiogenic agent through the penetrated element comprises providing the angiogenic agent to the controlled release matrix.

52. (Previously added) The process of claim 31 wherein:

said delivering the angiogenic agent includes providing a controlled release of the angiogenic agent over an extended period of time.

53. (Amended) The process of claim 31 wherein:

said inserting the device into the heart comprises inserting a distal end of a catheter into a chamber of the heart, with said catheter supporting the device at said distal end.

54. (Previously added) The process of claim 53 further including:

before causing the element to penetrate tissue inside the heart, using the catheter to position the element at a site selected for penetration.

55. (Previously added) The process of claim 53 further including:

after causing the element to penetrate tissue inside the heart, removing the catheter to leave the element implanted in the tissue.

56. (New) The process of claim 27 wherein:

said penetrating an element of a delivery device comprises causing the element to penetrate endocardial tissue.

57. (New) The process of claim 36 wherein:

said delivering an angiogenic growth factor comprises using a controlled release mechanism associated with at least one of the element and the catheter.

58. (New) The apparatus of claim 43 wherein:

said pharmacological agent is selected from the group consisting of: antiarrhythmic agents, angiogenic growth factors, anti-inflammatory agents, and their combinations.

59. (New) The apparatus of claim 29 further including:

a controlled release mechanism associated with at least one of the device and the catheter, for supplying a pharmacological agent to the cardiac tissue.

60. (New) The apparatus of claim 29 wherein:

the device, at least over an outermost portion thereof that includes a surface exposed when the device is secured at the designated site, is formed of an electrically conductive material.

61. (New) The apparatus of claim 30 wherein:

said pharmacological agent is selected from the group consisting of: antiarrhythmic agents, angiogenic growth factors, anti-inflammatory agents, and their combinations.

62. (New) The apparatus of claim 30 further including:

a controlled release mechanism associated with at least one of the device and the catheter, for supplying a pharmacological agent to the cardiac tissue.

63. (New) The apparatus of claim 30 wherein:

the tissue penetrating structure, at least over an outermost portion thereof that includes a surface exposed when the tissue penetrating structure is penetrated into heart tissue, is formed of an electrically conductive material.

64. (New) The process of claim 53 wherein:

said delivering an angiogenic agent comprises using a controlled release mechanism associated with at least one of the device and the catheter.

65. (New) A process for locally modifying electrical action in tissue at a designated site in the region of the heart; including:

using a delivery device to introduce a biocompatible, electrically inactive implantable device including a tissue penetrating element into the region of the heart, and to guide the implantable device to a designated site in said region;

causing the tissue penetrating element to penetrate tissue to secure the implantable device at the designated site; and

with the implantable device so secured, decoupling the delivery device from the implantable device, and withdrawing the delivery device from the designated site.

66. (New) The process of claim 65 wherein:

the delivery device comprises a catheter, and said using the catheter comprises intravascularly delivering the implantable device.

67. (New) The process of claim 65 wherein:

said causing the tissue penetrating element to penetrate tissue comprises manipulating a proximal end of the delivery device while the implantable device is coupled to a distal end of the delivery device.

68. (New) An apparatus for locally modifying electrical action in tissue at a designated site in the region of the heart, comprising:

a biocompatible, electrically inactive device including an element for penetrating tissue to secure the device at a designated site in the region of the heart, to modify electrical action in the tissue at the designated site; and

a catheter releasably coupled to the device to allow use of the catheter to deliver the device to the designated site, and further to allow a withdrawal of the catheter after securing the device.

69. (New) The apparatus of claim 68 wherein:

the catheter and the device are threadedly coupled.

70. (New) The apparatus of claim 68 wherein:

the device and the catheter are coupled through an elliptical coupling feature disposed at one end of the device.

71. (New) The apparatus of claim 68 wherein:

the penetrating element is helical.

72. (New) An apparatus implantable in tissue at a designated site in the region of the heart, including:

a biocompatible, electrically inactive implantable device comprising a tissue penetrating element for penetrating tissue to secure the implantable device at a designated site in the region of the heart, thereby to modify electrical action in tissue at the designated site;

wherein the implantable device further comprises a coupling structure for releasably coupling the implantable device to a delivery device to enable use of the delivery device to deliver the implantable device to the region of the heart, to position the implantable device at the designated location, and to cause the penetrating element to penetrate tissue to secure the implantable device at the designated site; and

wherein the coupling structure is adapted to allow a disengagement and removal of a delivery device from the implantable device, following use of the delivery device to so secure the implantable device.

73. (New) The apparatus of claim 72 further including:

a delivery device releasably coupled at a distal end thereof to the implantable device by said coupling structure, and operable at a proximal end thereof to cause the penetrating element to penetrate tissue to so secure the implantable device.

74. (New) The apparatus of claim 73 wherein:

the delivery device comprises an elongate catheter adapted to intravascularly deliver the implantable device.

75. (New) The apparatus of claim 73 wherein:

the delivery device comprises a stylet.

76. (New) The apparatus of claim 72 wherein:

the coupling structure comprises threads disposed at a proximal end of the implantable device.

77. (New) The apparatus of claim 72 wherein:

the coupling structure comprises an elliptical feature disposed at a proximal end of the implantable device.

78. (New) The apparatus of claim 72 wherein:

the tissue penetrating element is helical.

Status of Claims

The following claims have been cancelled from this application:

Claims 1-26 (of U.S. Patent No. 5,551,427).

The following claims are pending in this application:

Claims 27-55 (previously added); and

Claims 56-78 (added by this amendment).

Support for Amendments

A. Support for amendments to previously added claims, in U.S. Patent No. 5,551,427 (by column: lines):

1. For the reference in claims 27 and 28 to the penetrated element, and causing the element to penetrate heart tissue: (14:15-22).

B. Support for claims added by the present amendment, in U.S. Patent No. 5,551,427 (by column: lines):

1. Claim 56, reference to endocardial tissue: (14:15-17).

2. Claims 57, 59, 62 and 64 regarding a controlled release mechanism: (14:3-14).

3. Claims 58 and 61 regarding particular pharmacological agents: (6:9-16).

4. Claims 60 and 63 regarding an electrically conductive material: (9:52-56).

5. Claims 65, 68 and 72 regarding releasable coupling of an implantable device to a catheter or other delivery device: (11:5-9; 15:62-65).

6. Claims 66 and 74 regarding an intravascular catheter: (14:19-22; 12:66-67).

7. Claims 67 and 73 regarding manipulating the proximal end of the delivery device: (15:39-42).

8. Claims 69, 76 regarding a threaded coupling: (13:7-9).

9. Claims 70 and 77 regarding an elliptical coupling: (10:35-39).

10. Claims 71 and 78 regarding a helical element: (9:52-53).

11. Claim 75 regarding a stylet: (10:51-54).